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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,654	03/20/2001	Gilbert V. Levin	41272	9978

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EXAMINER	
OWENS JR, HOWARD V 5	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,654	LEVIN, GILBERT V.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Arguments

The following is in response to the amendment filed 12/18/02:

An action on the merits of claims 1-7 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections – 35 U.S.C. 112(1)

The rejection of claim 7 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons of record set forth below.

The instant claim is drawn to a method for promoting cardiovascular health in a mammal in need of such treatment comprising administering to said mammal an efficacious amount of tagatose, dosage of 50 to 1,500 mg/kg to raise the HDL level in the mammal; wherein the tagatose is D-tagatose, L-tagatose, or a mixture of the two isomers.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by relevant identifying or functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to show the applicant was in possession of the claimed genus. If the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlative. In the instant specification, the genus is that of tagatose. Applicant claims to be in possession of a method employing species of this genus, specifically L-tagatose or a mixture of L and D species in promoting cardiovascular health via elevation of HDL. Applicant's specification is based on a study using D-tagatose, exclusively for the elevation of HDL. There is no actual reduction to practice, support in the specification, nor nexus in the state of the art for

the use of L-tagatose or a mixture of D and L-tagatose to promote cardiovascular health via elevation of HDL levels in a mammal. The lone example presented on p. 2 of the specification seems to present a hypothetical treatment scenario that does not clearly lend support to whether applicant was in possession of the administration of L-tagatose or a mixture of the two isomers for a method of promoting cardiovascular health.

Applicant's representative asserts that applicant was in possession of the invention because p.2 of the specification clearly states that an efficacious amount of tagatose, i.e. D-tagatose, L-tagatose or a mixture of the two isomers may be administered to a mammal to increase the HDL level of the mammal. The instant rejection is a written description rejection, therefore the requirements for satisfying this rejection are not equivalent to that of 112(1) enablement or scope of enablement. Applicant is reminded that an adequate written description or the possession element thereof is not satisfied by an intention, wish or plan for obtaining the claimed chemical invention, *Eli Lilly*, 119 F.3d at 1566 (quoting *Fiers*, 984 F.2d at 1711); as such, the statement of intention set forth in the specification, "...D-tagatose, L-tagatose or a mixture of the two isomers may be administered to a mammal to increase the HDL level of the mammal..", does not alone constitute an adequate written description. Moreover, the USPTO guidelines clearly state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure. As cited supra, there is no actual reduction to practice, support in the specification, nor nexus in the state of the art for the use of L-tagatose or a mixture of D and L-tagatose to promote cardiovascular health via elevation of HDL levels in a mammal, therefore the rejection of record is maintained.

Claim Rejections - 35 U.S.C. 102/103

The rejection of claims 1-6 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zehner et al., U.S. Patent No. 5,356,879 is maintained for the reasons of record.

Claims 1-5 are drawn to a method for promoting cardiovascular health in a mammal in need of such treatment comprising administering to said mammal an efficacious amount of tagatose, dosage of 50 to 1,500 mg/kg to raise the HDL level in the mammal.

Claim 6 is drawn to the method of claim 1 wherein the tagatose is combined with a medication known to be useful in promoting cardiovascular health.

Zehner anticipates claims 1-5 as it teaches the administration of D-tagatose to a mammal, using a dosage within the claimed range, specifically 1 g/kg body weight (col.2, lines 45-60) to lower the rate of glycosylation end products that accumulate with age, that may be responsible for conditions such as arteriosclerosis, capillary angiopathy and heart disease (col.3, lines 21 – col. 4, line 33; and col.1, lines 40-47). Mammals who have arteriosclerosis would clearly be populations that would be in need of increasing levels of HDL; thus, per *Ex parte Nowitzki*, the administration of tagatose by Zehner to reduce the occurrence of complications such as arteriosclerosis due to accumulated glycosylation end products inherently anticipates applicant's intended use for increasing HDL and would clearly promote cardiovascular health.

Zehner however does not teach the combination of D-tagatose with a medication known to be useful in promoting cardiovascular health; however, it is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose, *In re Kerkoven,* 626 F.2d 846, 205 USPQ 1069 (C.C.P.A. 1980).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine D-tagatose with an agent useful in promoting cardiovascular health in a method for increasing the levels of HDL in a mammal.

A person of ordinary skill in the art would have been motivated to combine D-tagatose with an agent useful in promoting cardiovascular health in a method for increasing the levels of HDL in a mammal given that the agents have been recognized in the prior art as being individually useful for conditions associated with low HDL levels.

Applicant asserts that the inherency argument per *Ex Parte Nowitzki*, 26 USPQ2d, 1389 (Board of Patent Appeals and Interferences 1993) is properly refuted because "a person practicing the invention disclosed by Zehner et al. would not necessarily and inherently promote cardiovascular health in the individual being treated. Further, the patient being treated for

preventing the formation of advanced glycosylation end products by the method described by Zehner et al. would not necessarily be a patient in need of treatment for promoting cardiovascular health as required by the claims of this application". However, applicant's assertions do not confer with the teachings of the prior art of record. Contrary to applicant's statements, the purpose of treating the glycosylation end products is to promote cardiovascular health by preventing the cardiac problems presented with these end products, particularly atherosclerotic cardiovascular disease. As cited supra, mammals who have arteriosclerosis would clearly be populations that would be in need of increasing levels of HDL, thus it is unclear as to how applicant can regard these populations as being separate or distinct with regards to an inherency analysis. Applicant seeks to limit the teachings of Zehner to that of treating the aging process, but Zehner clearly teaches that cardiovascular complications associated with Diabetes Mellitus (DM) is also targeted with the use of D-tagatose in patients, therefore the assertion that Zehner is merely limited to treating the aging process is not convincing nor supported by the scope of the prior art teachings.

For the reasons cited supra, the 35 U.S.C. 102/103 rejection of record is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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